K133456

MAR - 7 2014

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M Deutschland GmbH

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number 9611385

Official Correspondent: .....Dr. Desi W. Soegiarto,

.....Regulatory Affairs Specialist

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Date:.....November 05, 2013

.....(revised on December 02, 2013)

Name of Devices

Proprietary Name:.....Flash AR

.....Flash AR Quick

Classification Name:.....Impression material

Common Name: .....Dental impression material

Predicate Devices

Flash AR Penta™, Flash AR Penta™ Quick
by 3M Deutschland GmbH, Germany K131404

Description for the Premarket Notification

Flash AR and Flash AR Quick are classified as impression materials (21 C.F.R. § 872.3660) because they are devices intended to reproduce the structure of a patient's teeth.

As the predicate devices Flash AR Penta™ and Flash AR Penta™ Quick (K131404), Flash AR and Flash AR Quick are medium-bodied (ISO Type 2) consistency A-silicone impression materials for all kinds of preliminary impressions. Like Flash AR Penta™ and Flash AR Penta™ Quick, Flash AR and Flash AR Quick are two component (base paste/catalyst) vinyl polysiloxane impression materials to be used for impressions, where typically alginates are used.

Whereas Flash AR Penta™ and Flash AR Penta™ Quick are designed to automatically be mixed and dispensed in all versions of Pentamix™ devices of 3M Deutschland GmbH and the mixing ratio for both materials is base paste:catalyst, 5:1 (by volume), Flash AR and Flash AR Quick will be delivered in Garant™ cartridges (50 ml plastic cartridges) and can be mixed and extruded using the Garant™ dispenser manufactured by 3M Deutschland GmbH with the mixing ratio for both materials of base paste:catalyst, 1:1 (by volume).

In this 510(k) premarket notification Flash AR and Flash AR Quick have been compared to the predicate devices with regard to indications for use, physical and mechanical properties, and chemical composition.

Test results according to ISO 4823 showed that Flash AR and Flash AR Quick are substantially equivalent to the predicate devices Flash AR Penta and Flash AR Penta Quick. Flash AR has same working time and intra-oral setting time as its predicate device Flash AR Penta, whereas working time and intra-oral setting time of Flash AR Quick are the same as those of its predicate device Flash AR Penta Quick. The indications for use of Flash AR and Flash AR Quick are the same as those of the predicate devices Flash AR Penta and Flash AR Penta Quick. Comparison for indications for use, performance data, and chemistry shows that Flash AR and Flash AR Quick are substantially equivalent to the predicate devices.

Biocompatibility testing was carried out. Biocompatibility evaluations have been performed for Flash AR and Flash AR Quick in consideration of FDA & internationally recognized guidelines. The conclusion of the assessments is that Flash AR and Flash AR Quick materials are biocompatible for its intended use.

In summary, it can be concluded that Flash AR and Flash AR Quick are substantially equivalent in safety and effectiveness as the predicate devices Flash AR Penta™ and Flash AR Penta™ Quick by 3M Deutschland GmbH, Germany (K131404).

Indications for Use:

- Impressions for the production of temporary restorations
- All types of preliminary impressions
- Impressions of the opposing jaw
- Impressions for orthodontic models

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

3M Deutschland GmbH
Dental Products
Desi Soegiarto, PhD
Regulatory Affairs Specialist
ESPE Platz
D-82229 Seefeld
GERMANY

Re: K133436
Trade/Device Name: Flash AR and Flash AR Quick
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: December 3, 2013
Received: December 6, 2013

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133434

Device Name: Flash AR
Flash AR Quick

Indications for Use:

- Impressions for the production of temporary restorations
- All types of preliminary impressions
- Impressions of the opposing jaw
- Impressions for orthodontic models

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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